

EXHIBIT 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.,)
Plaintiff,)
v.) CIVIL ACTION NO. 04-12457-PBS
ARTHREX, INC. and)
PEARSALLS LTD.)
Defendants.)
)

MEMORANDUM AND ORDER

January 31, 2007

Saris, U.S.D.J.

INTRODUCTION

Plaintiff DePuy Mitek, which specializes in the manufacture of surgical devices, alleges that Arthrex, Inc., and Pearsalls Ltd. (collectively "Arthrex"), two of Plaintiff's competitors, have infringed U.S. Patent No. 5,314,446 ("the '446 Patent"). Broadly, the '446 patent protects a braided surgical suture with two multi-filament yarns made from different materials. Beyond this definition, though, the parties disagree as to two key terms in the '446 Patent.

DePuy Mitek and Arthrex have moved for summary judgment on the issue of infringement. After a Markman hearing, the Court defines the two contested patent terms and **DENIES** without prejudice Plaintiff's motion for summary judgment of infringement and Defendants' motion for summary judgment of noninfringement.

FACTUAL BACKGROUND

1. The '446 Patent

The patent,¹ also known as the Hunter Patent, protects a sterilized heterogeneous braided suture. Claim One recites:

A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

- a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
- b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
- c) optionally a core

'446 Patent col.8-9 ll.63-68, 1-9 (emphasis added). The construction of the underlined terms "consisting essentially of" and "PE" are disputed.

2. Procedural History

On November 19, 2004, DePuy Mitek filed this "suture suit" against Arthrex, claiming that two of Arthrex's products - FiberWire® and TigerWire® - infringe the '446 patent. It amended its complaint on September 9, 2005 to include similar allegations

¹On May 24, 1994, the United States Patent and Trademark Office issued the '446 Patent, which was assigned to to Ethicon, Inc., a New Jersey based medical device company wholly owned by Johnson & Johnson. On August 9, 2004, Ethicon transferred its interest in the '446 Patent to DePuy Mitek, another Johnson & Johnson subsidiary. DePuy Mitek currently owns this patent.

against Pearsalls, the company responsible for manufacturing the materials and braids that ultimately become part of the FiberWire and TigerWire sutures sold by Arthrex.

FiberWire is a surgical suture that is formed by braiding together yarns of ultra high molecular weight polyethylene ("UHMWPE") and yarns of polyethylene terephthalate ("PET"). These yarns are braided together so that they are in direct intertwining contact with one another. The Defendants also add a silicone coating to the braided suture, which, they argue, significantly improves the handleability and pliability of the device. TigerWire, unlike FiberWire, is composed of a UHMWPE filament and a yarn of nylon. In all other material aspects, however, TigerWire is identical to FiberWire.² As such, this Court will refer to these products collectively as "FiberWire."

The Defendants argue that they do not infringe the patent because the UHMWPE utilized in the FiberWire suture is different from the "general purpose" PE described in Claim One. Second, the Defendants submit that the coating on the FiberWire suture removes the product from the scope of Claim One of the '446 Patent.

²As part of a motion to strike, the Defendants raise the possibility that TigerWire may be sufficiently dissimilar from FiberWire so as to warrant a separate examination of the two sutures. However, the differences between the two are not relevant to this opinion, although these distinctions may ultimately prove important.

DISCUSSION

1. Claim Construction

In construing a claim, this Court must first "look to the words of the claims themselves...to define the scope of the patented invention." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citation omitted). The language of the patent claims should be given first priority in the patent construction process because "the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

Terms in the patent claims "are generally given their ordinary and customary meaning." Vitronics, 90 F.3d at 1582. The Federal Circuit has held that "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1313 (citations omitted). This "inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." Id.

Despite the primary role that the plain meaning of the claim language plays in divining the subject matter of a patent, the

Federal Circuit has held that the plain language of the patents is best understood when viewed "in the context of the entire patent, including the specification." Id. Courts must examine the terms of the claim in light of the entire patent because

It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention - the inventor's lexicography - must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history.

Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998).

Therefore, in interpreting a given claim term, the Court should first look to all intrinsic evidence. First, the Court consults the claims themselves, which "provide substantial guidance as to the meaning of particular claim terms." Phillips, 415 F.3d at 1314 (quoting Vitronics, 90 F.3d at 1582). By examining "the context of the surrounding words of the [disputed] claim," an interpreter may properly comprehend and "determin[e] the ordinary and customary meaning of those [disputed] terms." ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003).

Second, the Court must properly weigh the "specification

that concludes with the claims.” Phillips, 415 F.3d at 1315. Therefore, the claims of a patent “must be read in view of the specification, of which they are a part.” Id. (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995)). As a consequence, the Federal Circuit has opined: “The specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). Thus, the specifications should guide this Court in its study of the evidence presented by the patent.

Finally, as part of this intrinsic evidence analysis, the Court “should also consider the patent’s prosecution history, if it is in evidence.” Markman, 52 F.3d at 980. “Like the specification,” the Federal Circuit has suggested that “the prosecution history provides evidence of how the PTO and the inventor understood the patent.” Phillips, 415 F.3d at 1317. Nevertheless, the Court has cautioned that prosecution histories, unlike other forms of intrinsic evidence, “often lack[] the clarity of the specification and thus [are] less useful for claim construction purposes.” Id. (citations omitted).

In contrast to the intrinsic evidence analysis endorsed by the Court in Phillips, extrinsic evidence, “consist[ing] of all evidence external to the patent and prosecution history,

including expert and inventor testimony, dictionaries, and learned treatises," is less favored in the claim construction analysis. Markman, 52 F.3d at 980 (citing Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 546 (1870)). Although the Court has expressly "authorized district courts to rely on extrinsic evidence," Phillips, 415 F.3d at 1317, the Federal Court warned that such exogenous evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)). Therefore, the Court has resolved to "emphasize[] the importance of intrinsic evidence in claim construction" because "extrinsic evidence...is unlikely to result in a reliable interpretation of patent claim scope." Phillips, 415 F.3d at 1319.

A. Meaning of "PE"

The parties dispute the proper scope of the term "PE" in the context of the '446 patent. Plaintiff contends that PE includes any polymer formed from a repeating ethylene monomer, including ultra high molecular weight polyethylene. By contrast, the Defendants argue that the term "PE" in the claims refers to general purpose PE, which excludes UHMWPE.

Plaintiff's expert, Dr. Matthew Hermes, provided the

scientific background, which is largely undisputed. PE is formed from repeating units of the monomer ethylene, (CH₂-CH₂). (Pl.'s Markman Br. Ex. 7 at ¶ 6.) PE may be referred to as (CH₂-CH₂)_n, where n equals a whole number and indicates the number of repeating monomeric units of ethylene in the polymer. The "molecular weight" of a PE chain is determined by the length of the chain (i.e., how high n is). UHMWPE is composed of the same monomer unit as any other polyethylene chain, but has a longer chain of the repeating ethylene monomer than "low molecular weight" or "medium molecular weight" PE. (Id. at ¶ 7.) In other words, the building block for a suture made from UHMWPE is a very long and heavy PE chain.

Claim One recites that the first yarn is composed of a fiber-forming material "from the group consisting of" seven specific polymers, including PE. The specification is clear that "PE" means polyethylene. '446 Patent col.4 l.27. This claim does not distinguish between kinds of PE possessing different molecular weights. The patentee did not limit the definition of PE. Cf. Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1373 (Fed. Cir. 2005) (determining that the claim term "saccharide" should not be construed only to include polysaccharides having ten or less monomer units because the claim, like the specifications, did not contemplate such a limited definition).

Plaintiff has also introduced evidence that a person having ordinary skill in the art would understand PE to mean all polymers made from PE. Dr. Hermes opines: "One of skill in the art would have known that 'PE' means 'polyethylene' and means all polymers made from ethylene. PE is the generic name for all types of PE, including ultra high molecular weight PE." (Pl.'s Markman Br. Ex 7 at ¶ 9.) To support Dr. Hermes's opinion, DePuy Mitek points to several technical dictionaries stating that the term PE encompasses all polymers consisting of ethylene monomers, including UHMWPE. For instance, the Encyclopedia of Polymer Science and Engineering states that "polyethylene [is] the 'common (source-based)' name for all polymers made from ethylene." (Pl.'s Markman Br. Ex. 7, Tab B).

The Defendants, however, argue that UHMWPE is a rigid and inflexible synthetic compound that would never enhance the pliability or lubricity of a suture.³ As one of Arthrex's experts, Dr. Debi Prasad Mukherjee, argues:

In February 1992, UHMWPE was a well-known, highly specialized fiber material with strength properties that are far superior to those of general purpose PE. Consequently, the two materials are generally used for very different applications and one is not a substitute for the other. It has been my experience that,

³Plaintiff has introduced evidence that UHMWPE is lubricious. (See Plaintiff's Ex. 9 at 51:15-55:5). The parties do not clearly explain the difference, if any, between a lubricious material and a stiff material in the context of a suture. Both appear to be related to handleability and pliability.

generally, when UHMWPE is intended to be included for a specified application, there is a special effort to make that fact known.

(Def.'s Markman Br. Ex. 12.) Although there is evidence that a person of ordinary skill in the art would understand that UHMWPE has different properties from other kinds of PE, Arthrex has introduced no evidence that one of ordinary skill would not understand the term PE to include UHMWPE.

Defendants argue that the prosecution history contains a disclaimer of the polymer UHMWPE, citing extensively to the discussion of the "Burgess reference" in the '446 Patent's history. (Def.'s Markman Br. Ex. 7-8.) The Burgess patent protects a type of braided fishing line that utilizes a high-tensile PE as part of its construction. In response to the rejection by the patent examiner of the suture claims based on the Burgess patent application, the applicant argued:

One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement maybe the most important requirement for a braided suture. This is so because the suture knot is what keeps a stitched wound intact.

(DM1000196). (Emphasis in original). The applicant distinguishes Burgess: "In contrast, knot strength is not even mentioned in Burgess." (Id.) The applicant adds: "Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line minimal stretchability....Although this thread has great strength

properties, it suffers from low elongation and, in turn, poor knot strength properties." (DMI000196). (Emphasis in original). The parties agree that "high-tensile polythene" is the European terminology for UHMWPE.

In overcoming the Burgess reference, the applicant does distinguish the suture from the fishing wire by drawing a distinction between materials used in the invention, pointing out the poor knot strength properties of high-tensile polythene. The Defendants argue that in distinguishing the heterogeneous braided suture from the fishing line composed of UHMWPE, the patentee limited the scope of its patent to ordinary general use PE. (Def.'s Markman Br. 12-13).

Plaintiff responds that the prosecution history is not a clear disclaimer of the UHMWPE. It emphasizes that the patent examiner and the applicant both routinely refer to the "high tensile polythene" described by the British Burgess patent as "polyethylene." (See, e.g., Pl.'s Markman Br. Ex. 3 at DMI000189.) By including "PE" in the list of polymers in the amended claim, Plaintiff contends, the inventors intended to include UHMWPE. Moreover, while the prosecution history does indicate that UHMWPE was not a preferred polymer because of its minimal stretchability, the applicant emphasized the distinction between the uses and purposes of the two devices:

In view of the dissimilarities in property requirements between sutures and fishing line, there would be no

incentive for a medical designer who wishes to improve the properties of a braided suture to study the art related to braided fishing lines. Even if he did use the teachings of fishing line art to modify a suture, then he would inevitably design an unacceptable suture.

(Pl.'s Markman Br. Ex. 3 at DMI000196-97.) In light of this language, Plaintiff's argument that there was never a clear disclaimer of UHMWPE is ultimately persuasive. See Andersen Corp. v. Fiber Composites, LLC, Nos. 05-1434, 06-1009, ____ F.3d ____, 2007 WL 188709, at *10 (Fed. Cir. Jan. 26, 2007) (citing Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1375 (Fed. Cir. 2005)) ("It is true that we have warned against importing limitations from the specification into the claims absent a clear disclaimer of claim scope.").

Pulling together all of these threads, this Court finds that an ordinary person skilled in the art of science and suture manufacturing looking to the plain language of the claim, the specification, and the prosecution history of the '446 Patent would conclude that "PE," as used in Claim 1, includes all polymers formed from a repeating ethylene monomer, including UHMWPE.

B. Meaning of "Consisting Essentially Of"

The second term disputed by the parties is the transitional phrase "consisting essentially of." Generally, three transitional terms are used in patent claims: (1) "comprising," which is an open term of transition (2) "consisting of," which is

a closed term of transition, and (3) "consisting essentially of," which is a partially open term perched between the extremes of the other two phrases. "In view of the ambiguous nature of the phrase," the Federal Circuit has opined that "consisting essentially of" "has long been understood to permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'" AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1239 (Fed. Cir. 2003) (quoting PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998)).

To determine those "basic and novel properties of the invention," the Court must look at the specification to determine "the goal of the invention as well as what distinguishes it from prior art." AK Steel, 344 F.3d at 1239-40 (holding that a limiting statement in the specification that silicon should not exceed 0.5% was a disclaimer which had an impact upon the meaning of the phrase "consisting essentially of aluminum.") The Court must also look at the prosecution history of a patent to determine whether an unlisted ingredient was excluded from the scope of a "consisting essentially of" claim. PPG, 156 F.3d at 1355.

Construing the "consisting essentially of" language in a patent claim can "at times blur the distinction between the separate steps in an infringement analysis." AK Steel, 344 F.3d

at 1240. Where the specification and/or prosecution history directly speaks to and conclusively answers the question of what constitutes a material effect, the issue may be resolved as a question of law. Id. In some situations, however, whether an additional ingredient materially affects the basic and novel characteristics of a patented invention is a question of fact for a jury. See PPG, 156 F.3d at 1357 (stating that it is the province of the jury to determine whether the iron sulfide had a material affect on the basic and novel characteristics of the patented glass).

The key question of claim construction for this term in Claim One involves discerning the basic and novel properties of the heterogeneous suture. Once this determination has been made, the Court can attempt to resolve the parties' disagreement over whether the surgical coating placed on FiberWire braided suture "materially affects" the basic and novel properties of the suture described by the '446 Patent. AK Steel, 344 F.3d at 1239.

The Defendants submit that this Court should construe the claim term "consisting essentially of" as follows:

- i) The claimed surgical suture excludes additional ingredients that materially affect the basic and novel characteristics of the claimed invention.
- ii) The basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.

(Def.'s Markman Br. 16.) By contrast DePuy Mitek suggests:

The 'novel and basic characteristics' of the invention are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the materials claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. *Consisting essentially of* excludes sutures that contain bioabsorbable materials as the first and second fiber-forming materials.

(emphasis in original) (Pl.'s Markman Br. 8.)

DePuy Mitek's primary argument is that the transitional phrase was inserted to exclude certain bioabsorbable materials in the prior art from the patent claims. The prosecution history demonstrates the "consisting essentially of" language was added by amendment. In the prosecution history, the examiner originally had rejected the claims based on two references - Doddi and Kaplan - which included braids of dissimilar materials. Plaintiff argues it amended the claims to exclude bioabsorbable materials from the first and second fiber-forming materials in order to further distance itself from this prior art.

In response to the examiner's rejection for anticipation by Kaplan, the applicant stated that in Kaplan, the "sheath yarn" was a "biocompatible yarn that is bioabsorbable or semi-bioabsorbable...In one embodiment the sheath yarn could also contain a non bio-absorbable yarn of one or more chemical compositions....Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn." (DMI 1000259). (Emphasis

added). Later, the applicant again distinguishes the prior art: "Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e., PTFE) and a second set of nonabsorbable yarn (i.e., PET). (DM 1000260).⁴ Id. Thus the Plaintiff argues there is a clear and express disclaimer of bioabsorbable yarns in the prosecution history. SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1286 (Fed. Cir. 2005).

Defendants contend that the prosecution history does not support this interpretation because the patent specification provides, "The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired."

'446 Patent col.3 ll.63-65 (emphasis added). Still, under the doctrine of prosecution disclaimer, Plaintiff's argument that it clearly disclaimed bioabsorbable yarns to overcome the rejection seems persuasive. Nonetheless, this debate seems largely beside the point because the issue here involves coatings, not bioabsorbable yarns.

The Defendants contend that the invention's primary basic and novel characteristic is that it improves the handleability and pliability of a suture without significantly sacrificing any physical properties of the constituent materials of the device, like strength or knot tiedown. The specifications reveal that

⁴In addition, the plaintiff pointed out that Kaplan taught that sheath yarns listed in the invention should not be used in sheaths.

the mechanical braiding of the two dissimilar fibers was intended to enhance the overall pliability of the device. As the "Background of the Invention" section notes, "the enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament." '446 Patent col.1 ll.12-15. For this reason, the inventors eschewed "any mechanism which reduces this individual fiber mobility." Id. at col.1 ll.18-19. The specification states that the invention relates to "sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures." Id. at col. 1 ll. 6-8. These "[b]raided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts." Id. at col.1 ll.8-10. The specification points out, "Unfortunately, the prior art abounds with attempts to improve specific properties of multi-filament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multi-filament sutures almost universally possess a surface coating to improve handling properties." Id. at col. 1 ll. 26-31. It continues: "All of the attempts described in the prior art have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability." Id. at col. 2 ll. 14-17. Of significance, the specification states:

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties."

Id. at col.2 ll. 32-37 (Emphasis added).

Plaintiff argues that increased pliability is a property only of the preferred embodiment, pointing to the passage that states: "For example, in preferred embodiments, the heterogenous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security." Id. at col. 2 ll. 50-67. As shown above, this is a myopic view of the specification, which states throughout that a primary goal of the invention is to achieve enhanced pliability and handleability. The sterilized heterogeneous braids described in this patent seek to achieve a high degree of pliability and handleability by mechanically blending together two dissimilar synthetic yarns.

Therefore, this Court concludes that the basic and novel properties of the suture described in the '446 Patent are: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability

without significantly sacrificing the physical properties of the constituent elements of the suture.

2. Summary Judgment

As noted previously, both DePuy Mitek and Arthrex have moved for summary judgment on the issue of patent infringement. However, the summary judgment record is a mess because of the multiple motions to strike, each with extensive appendices and confusing briefing. This Court has allowed Arthrex to supplement Dr. Gitis's expert report to correct certain typographical and computational errors. Moreover, DePuy Mitek has launched a Daubert challenge to Defendants' expert report, and it is difficult to figure out the various expert opinions on the affect of the coatings on the accused devices. Accordingly, this Court will deny these cross-motions for summary judgment without prejudice.

ORDER

Plaintiff's motion for summary judgment of infringement is DENIED without prejudice (Docket No. 36). Defendants' motion for summary judgment of noninfringement is DENIED without prejudice (Docket No. 39).

All parties are ordered to submit a single brief, not to exceed 20 pages, on the summary judgment issue of patent infringement within 60 days in light of the Court's construction of the '446 Patent. The parties shall file no additional motions

to strike, and there shall be no replies or sur-replies.

Patti B. Saris
PATTI B. SARIS
United States District Judge